CLAIMS

What is claimed is:

1. A sheath, comprising:

a hollow body capable of removably covering at least a portion of a device, said device carries a therapeutic substance which can be delivered to a subject, wherein said body comprises a layer that prevents said therapeutic substance from significantly absorbing into said body.

2. The sheath of Claim 1, wherein said device is a stent.

3. The sheath of Claim 1, wherein said device is a balloon.

4. The sheath of Claim 1, wherein said layer is made from a polymeric material selected from a group of polyolefins, polyurethanes, cellulosics, polyesters, polyamides, poly(hexamethylene isophthalamide/terephthalamide), poly(ethylene terephthalate-co-p-oxybenzoate), poly(hydroxy amide ethers), polyacrylates, polyacrylonitrile, acrylonitrile/styrene copolymer, rubber-modified acrylonitrile/acrylate copolymer, poly(methyl methacrylate), liquid crystal polymers, poly(phenylene sulfide), polystyrenes, polycarbonates, poly(vinyl alcohols), poly(ethylene-vinyl alcohol), epoxies composed of bisphenol A based diepoxides with amine cure, aliphatic polyketones, polysulfones, poly(ester-sulfone), poly(urethane-sulfone), poly(carbonate-sulfone), poly(3-hydroxyoxetane), poly(amino ethers), gelatin, amylose, parylene-C, parylene-D, parylene-N, and mixture thereof.

5. The sheath of Claim 4, wherein said polyolefins are selected from a group of polyethylenes, poly (vinyl chloride), poly (vinylidene chloride), poly (vinyl fluoride), poly (vinylidene fluoride), poly (tetrafluoroethylene), poly (chlorotrifluoroethylene), and mixtures thereof.

6. The sheath of Claim 4, wherein said polyurethane has a glass transition temperature above a storage temperature.

7. The sheath of Claim 4, wherein said polyurethane has a non-polar soft segment, said non-polar soft segment is selected from the group of hydrocarbons, silicones, fluorosilicones, and mixtures thereof.

8. The sheath of Claim 4, wherein said cellulosics are selected from the group of cellulose acetate having a DS greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, and mixtures thereof.

9. The sheath of Claim 4, wherein said polyesters are selected from a group of poly (ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly (butylene terephthalate), and mixtures thereof.

10. The sheath of Claim 4, wherein said polyamides are selected from a group of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof.

11. The sheath of Claim 1, wherein said layer is made from a polymeric material and a predetermined amount of fillers added to said polymeric material.

12. The sheath of Claim 1, wherein said layer is made from glass.

13. The sheath of Claim 1, wherein said layer is made from a metallic material.

14. The sheath of Claim 1, wherein said layer comprises a therapeutic substance contacting surface, a metallic substance disposed on said therapeutic substance contacting surface.

15. The sheath of Claim 1, wherein said layer comprises a therapeutic substance contacting surface, said therapeutic substance contacting surface has a coating of a main group element oxide formed thereon, said main group element oxide coating is selected from a group of silicon oxide and metal oxide.

16. A medical assembly, comprising:

(a) a catheter assembly;

(b) a balloon disposed on said catheter assembly, said balloon capable of delivering a therapeutic substance to a subject; and

(c) a sheath removably covering said balloon, said sheath comprises a layer made from a first barrier material which prevents said therapeutic substance from significantly diffusing into said first barrier material.

17. The medical assembly of Claim 16, wherein said balloon is defined by a balloon wall, said balloon wall is made from a second barrier material which prevents said therapeutic substance from significantly diffusing into said second barrier material.

18. The medical assembly of Claim 17, wherein said second barrier material has an oxygen transmission rate of not more than about 200 cc/100 in^2, for 1 mil per 24 hrs. at 73° F, 75% relative humidity, and 1 atm.

19. The medical assembly of Claim 17, wherein said second barrier material has a water vapor transmission rate of not more than 20 gm/100 in^2 for 1 mil per 24 hrs. at 100° F (38° C), 90% relative humidity, and 1 atm (760 mm Hg).

20. The medical assembly of Claim 16, wherein said balloon is defined by a balloon wall and a barrier layer formed on at least a portion of said balloon wall, said barrier layer is made from a second barrier material which prevents said therapeutic substance from significantly penetrating into said second barrier layer.

21. The medical assembly of Claim 20, wherein said second barrier material has an oxygen transmission rate of not more than about 200 cc/100 in^2, for 1 mil per 24 hrs. at 73° F, 75% relative humidity, and 1 atm.

22. The medical assembly of Claim 20, wherein said second barrier material has a water vapor transmission rate of not more than 20 gm/100 in^2 for 1 mil per 24 hrs. at 100° F, 90% relative humidity, and 1 atm.

23. The medical assembly of Claim 16, wherein said first barrier material has an oxygen transmission rate of not more than about 200 cc/100 in^2, for 1 mil per 24 hrs. at 73° F, 75% relative humidity, and 1 atm.

24. The medical assembly of Claim 16, wherein said first barrier material has a water vapor transmission rate of not more than 20 gm/100 in^2 for 1 mil per 24 hrs. at 100° F, 90% relative humidity, and 1 atm.

25. A method of preventing a therapeutic substance from significantly diffusing from a device, said device is configured to deliver said therapeutic substance to a subject, comprising the act of:

removably covering at least a portion of said device with a sheath, said sheath comprising a layer having an inside surface in contact with said device, said layer is formed from a material which prevents significant diffusion of said substance from said device.

26. The method of Claim 25, wherein said device is a stent.

27. The method of Claim 25, wherein said material comprises a polymer selected from a group of polyolefins, polyurethanes, cellulosics, polyesters, polyamides, poly(hexamethylene isophthalamide/terephthalamide), poly(ethylene terephthalate-co-p-oxybenzoate), poly(hydroxy amide ethers), polyacrylates, polyacrylonitrile, acrylonitrile/styrene copolymer, rubber-modified acrylonitrile/acrylate copolymer, poly(methyl methacrylate), liquid crystal polymers, poly(phenylene sulfide), polystyrenes, polycarbonates, poly(vinyl alcohols), poly(ethylene-vinyl alcohol), epoxies composed of bisphenol A based diepoxides with amine cure, aliphatic polyketones, polysulfones, poly(ester-sulfone), poly(urethane-sulfone), poly(carbonate-sulfone), poly(3-hydroxyoxetane), poly(amino ethers), gelatin, amylose, parylene-C, parylene-D, parylene-N, and mixture thereof.

28. The method of Claim 27, wherein said polyolefins are selected from a group of polyethylenes, poly (vinyl chloride), poly (vinylidene chloride), poly (vinyl fluoride), poly (vinylidene fluoride), poly (tetrafluoroethylene), poly (chlorotrifluoroethylene), and mixtures thereof.

29. The method of Claim 27, wherein said polyurethane has a glass transition temperature above a storage temperature.

30. The method of Claim 27, wherein said polyurethane has a non-polar soft segment, said non-polar soft segment is selected from the group of hydrocarbons, silicones, fluorosilicones, and mixtures thereof.

31. The method of Claim 27, wherein said cellulosics are selected from the group of cellulose acetate having a DS greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, and mixtures thereof.

32. The method of Claim 27, wherein said polyesters are selected from a group of poly (ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), and poly (butylene terephthalate).

33. The method of Claim 27, wherein said polyamides are selected from a group of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof.

34. The method of Claim 25, wherein said layer is made from a polymeric material and a predetermined amount of fillers added to said polymeric material.

35. The method of Claim 25, wherein said layer is made from glass.

36. The method of Claim 25, wherein said layer is made from a metallic material.

37. The method of Claim 25, wherein said inside surface of said layer has a metallic substance disposed thereon.

38. The method of Claim 25, wherein said inside surface of said layer has a coating of a main group element oxide formed thereon, said main group element oxide coating is selected from a group of silicon oxide and metal oxide.

39. A balloon for a catheter assembly comprising a layer made formed from a polymeric material selected from a group of polyolefins, polyurethanes, cellulosics, polyesters, polyamides, poly(hexamethylene isophthalamide/terephthalamide), poly(ethylene terephthalate-co-p-oxybenzoate), poly(hydroxy amide ethers), polyacrylates, polyacrylonitrile, acrylonitrile/styrene copolymer, rubber-modified acrylonitrile/acrylate copolymer, poly(methyl methacrylate), liquid crystal polymers, poly(phenylene sulfide), polystyrenes, polycarbonates, poly(vinyl alcohols), poly(ethylene-vinyl alcohol), epoxies composed of bisphenol A based diepoxides with amine cure, aliphatic polyketones, polysulfones, poly(ester-sulfone), poly(urethane-sulfone), poly(carbonate-sulfone), poly(3-hydroxyoxetane), poly(amino ethers), gelatin, amylose, parylene-C, parylene-D, parylene-N, and mixture thereof.

40. The balloon of Claim 39, wherein said polyolefins are selected from a group of polyethylenes, poly (vinyl chloride), poly (vinylidene chloride), poly (vinyl fluoride), poly (vinylidene fluoride), poly (tetrafluoroethylene), poly (chlorotrifluoroethylene), and mixtures thereof.

41. The balloon of Claim 39, wherein said polyurethane has a glass transition temperature above a storage temperature.

42. The balloon of Claim 39, wherein said polyurethane has a non-polar soft segment, said non-polar soft segment is selected from the group of hydrocarbons, silicones, fluorosilicones, and mixtures thereof.

43. The balloon of Claim 39, wherein said cellulosics are selected from the group of cellulose acetate having a DS greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, and mixtures thereof.

44. The balloon of Claim 39, wherein said polyesters are selected from a group of poly (ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), and poly (butylene terephthalate).

45. The balloon of Claim 39, wherein said polyamides are selected from a group of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof.

46. The balloon of Claim 39, wherein layer defines a balloon wall for said balloon of said catheter assembly, said balloon wall is capable of inflating to dilate from a collapsed configuration to an expanded configuration and to selectively deflate from said expanded configuration to said collapsed configuration.

47. The balloon of Claim 39, wherein said balloon is defined by a balloon wall which is capable of inflating to dilate from a collapsed configuration to an expanded configuration and to selectively deflate from said expanded configuration to said collapsed configuration, wherein said layer is disposed on at least a portion of said balloon wall.

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